

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:4253
ANSWERED ON:24.08.2005
REGULATION OF MEDICAL DEVICES
Chitthan Shri N.S.V.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether the Government is considering to bring a large number of unregulated medical devices under the purview of the Drugs & Cosmetics Act to ensure the quality of implementation;
- (b) if so, the details thereof and if not, the reasons therefor;
- (c) whether the Government has issued any guidelines to Pharmaceuticals in this regard;
- (d) if so, the details thereof; and
- (e) if not, the reasons therefor?

Answer

THE MINISTER OF HEALTH & FAMILY WELFARE (DR.ANBUMANI RAMADOSS)

- (a) & (b): Yes, Sir. The Drugs Technical Advisory Board, in its meeting on 2nd August, 2005 has recommended to notify sterile medical devices including stents, Catheters, Intra Ocular Lens, IV Connula, Bone Cement, Heart Valve, Scalp Vein Set, Orthopedics Implants and Internal Prosthetic replacements under Section 3(b) (iv) of the Drugs and Cosmetics Act.
- (c): No, Sir.
- (d) & (e): Does not arise.